RVD2009-10

Re-evaluation Decision

Imazamethabenz-Methyl

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Re-evaluation Decision for Imazamethabenz-Methyl

After a re-evaluation of the herbicide imazamethabenz-methyl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing imazamethabenz-methyl for sale and use in Canada.

An evaluation of available scientific information found that under the revised conditions of use, products containing imazamethabenz-methyl have value in the food and crop industry and do not present unacceptable risks to human health or the environment. As a condition of the continued registration of imazamethabenz-methyl, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of imazamethabenz-methyl was first presented in Proposed Re-evaluation Decision PRVD2008-29, *Imazamethabenz-methyl*.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of imazamethabenz-methyl, summarizes the Agency's decision and the reasons for it.

Appendix I summarizes the comments received during the consultation process and the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-29, *Imazamethabenz-methyl*. To comply with this decision, registrants of products containing imazamethabenz-methyl will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-29, *Imazamethabenz-methyl*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risks are considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product, under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include, special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive populations in humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides.

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

What Is Imazamethabenz-Methyl?

Imazamethabenz-methyl is a selective systemic herbicide registered for postemergent use on wheat (spring and durum) and spring barley. It is registered for use in the Prairie provinces and the Peace River region, the Okanagan Valley and the Creston Flats areas of British Columbia on sunflower and annual ryegrass grown only for seed in the Prairie provinces. Imazamethabenz-methyl can also be used to control wild oats and broadleaf weeds including; wild mustard, stinkweed, wild buckwheat and tartary buckwheat. It is applied once per year at a rate of 250 to 500 g a.i./ha by ground equipment only.

Health Considerations

Can Approved Uses of Imazamethabenz-Methyl Affect Human Health?

Imazamethabenz-methyl is unlikely to affect your health when used according to the revised label directions.

Potential exposure to imazamethabenz-methyl may occur through diet (food and water), when handling and applying the product or by prematurely entering treated sites. When assessing health risks, two key factors are considered: the levels at which health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed, when imazamethabenz-methyl products are used according to label directions.

Imazamethabenz-methyl was slightly irritating to the eyes, but was not irritating to the skin of rabbits nor was it a sensitizer in guinea pigs. Consequently, no hazard statements are required on the label of the technical class product.

Imazamethabenz-methyl did not cause cancer in animals, was not genotoxic or teratogenic and showed no signs of neurotoxicity. The liver was the main target of toxicity in rats. The first signs of toxicity in dogs given daily doses of imazamethabenz-methyl over longer periods of time were slight changes in haematology, along with effects on organ weights and decreased body weight. In mice, effects on organ weights were also noted at high doses.

When imazamethabenz-methyl was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to imazamethabenz-methyl than the adult animal. The risk assessment protects against these effects, by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that over a lifetime, is believed to have no significant harmful effects.

Human exposure to imazamethabenz-methyl was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulation (e.g. children one to six years old). Conservative assumptions were used to reflect the magnitude of the residues as well as the percent crop treated. As well, information on drinking water was used to estimate both the acute and chronic aggregate exposures and risks.

Only long term (chronic) exposure estimates were determined for different subpopulations representing different ages, genders and reproductive status. Acute and cancer dietary assessments were not required.

Aggregate chronic exposure (i.e. to imazamethabenz-methyl from food and drinking water) represented 6% and 23% of the chronic reference dose for the general population and non-nursing infants, respectively, when using drinking water modelling. As a result, chronic risks were below the PMRA's level of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain

foods. Food containing a pesticide residue that does not exceed the established MRL, does not pose an unacceptable health risk.

MRLs for imazamethabenz-methyl are currently specified for barley, sunflower and wheat. No modification of the MRLs was proposed during the course of the re-evaluation. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The MRLs for imazamethabenz-methyl can be found in PRVD2008-29, Science Evaluation, Table 8.1.1.3.

Risks in Residential and Other Non-Occupational Environments

Residential and other non-occupational risks are not of concern.

Imazamethabenz-methyl is not registered for use in any residential areas; therefore, a non-occupational risk assessment was not required.

Occupational Risks From Handling Imazamethabenz-Methyl

Occupational risks are not of concern when used according to the revised label directions.

Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation and considering the use of appropriate protective equipment, the risk estimates associated with mixing, loading and applying activities meet current standards for all the scenarios and are not of concern. The personal protective equipment is long pants, long-sleeved shirt, shoes plus socks and chemical-resistant gloves.

Postapplication risks are not of concern when used according to the revised label directions.

Occupational postappiication risk assessments consider exposures of workers entering treated agricultural sites. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation and considering the updated protective measures (revised restricted-entry interval), postapplication risk estimates to re-entry workers performing scouting activities meet current standards and are not of concern.

Environmental Considerations

What Happens When Imazamethabenz-Methyl Is Introduced Into the Environment?

Imazamethabenz-methyl poses a potential risk to terrestrial and aquatic plants; therefore, additional risk reduction measures need to be observed

When imazamethabenz-methyl is applied to control weeds in crops, some of it finds its way into soil and water. The chemical is expected to be slightly persistent to non-persistent in soil as it is degraded by soil microbes. It is non-persistent to moderately persistent in alkaline and acidic water, respectively. Both imazamethabenz-methyl and its breakdown product imazamethabenz-methyl acid are mobile and hence can move freely in soil. The high solubility, the leaching studies and the results of the adsorption/desorption studies indicate that imazamethabenz-methyl and imazamethabenz-methyl acid have the potential to reach groundwater. However, field evidence indicates that imazamethabenz-methyl alone remains within the top 15 cm of the soil after application. Water monitoring of ponds and rivers have revealed residues from runoff, but at concentrations below levels of concern for aquatic life. Several major transformation products from the breakdown of imazamethabenz-methyl would be present in soil and aquatic systems, but their fate in the environment especially that of imazamethabenz-methyl acid, have not been fully characterized.

When imazamethabenz-methyl is used for weed control in crops, there is a potential that sensitive plant species on land and in water may be exposed to the chemical as a result of the spray drift and runoff. Some of these species are sensitive to the chemical and would be adversely affected. To reduce effects in non-target areas, spray buffer zones between the agricultural field and the non-target terrestrial or aquatic areas must be implemented. The width of these buffer zones will be specified on the product label. Imazamethabenz-methyl presents negligible risk to wild birds, mammals, bees, earthworms, fish, amphibians, aquatic invertebrates and algae because concentrations in the environments are expected to be at levels that are not harmful.

Value Considerations

What Is the Value of Imazamethabenz-Methyl?

Imazamethabenz-methyl controls wild oats and some broadleaf weeds in several crops.

In Western Canada, imazamethabenz-methyl reduces a portion of the estimated $343.9 million in economic losses incurred by weeds for barley, wheat and sunflower. It is one of two herbicides used for the control of wild mustard and stinkweed in sunflower and annual ryegrass grown only for seed. Imazamethabenz-methyl can be tank-mixed with other herbicides, to broaden the spectrum of weed control. Although populations of

imazamethabenz-methyl-resistant wild oats have been identified in Canada, imazamethabenz-methyl can readily be used in locations lacking resistant populations in rotation with other herbicide groups including Groups 1, 3, 8, 9, 10, 11 or 16, to mitigate resistance development in populations of wild oats. Being a Group 2 herbicide, imazamethabenz-methyl plays a role in managing resistance development to other herbicide groups.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of imazamethabenz-methyl, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Mixers, loaders and applicators must wear a long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves. Gloves not required for groundboom sprayers.
- Workers must not re-enter treated fields until 12 hours after application.
- Application must only occur when the potential for drift to areas of human habitation or activity (i.e. houses, cottages, schools and recreational areas) is minimal. Applicators must take into consideration wind speed, wind direction, temperature, the application equipment used and sprayer settings.

Environment

- Updated precautionary statements and terrestrial and aquatic buffer zones (0 to 1 m) are required, to protect terrestrial and aquatic habitats that may contain sensitive plant species.

Other Information

For imazamethabenz-methyl, the summary of assessments found in PRVD2008-29 serves as an evaluation report. The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this decision on imazamethabenz-methyl, within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comment and Response

1.0 Comment on the Specificity of the Analytical Method

The PRVD (Appendix IX) indicated that there were detections of imazamethabenz-methyl in water monitoring programs, in regions of Canada where imazamethabenz-methyl was not used. The registrant questioned if the analytical method was specific to imazamethabenz-methyl or whether the detections may have been non-specific, as there are numerous imidazolinone herbicides used in these regions.

Response

Although imazamethabenz-methyl is restricted to the Prairie provinces and specific areas in British Columbia, various monitoring studies were conducted in Ontario as part of the Environment Canada's routine monitoring program. However, imazamethabenz-methyl levels were below level of concern. The analytical method was specific for imazamethabenz-methyl.